

**REMARKS**

Claims 1-15 and 17 are pending in this application. Claim 16 has been canceled and its limitations have been incorporated in amended independent claim 14. Claims 1, 3, 8, 9, 14 and 15 have been amended. No new matter has been introduced.

Claims 1-4 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Filho (U.S. Patent No. 6,089,867) ("Filho") in view of Applicant's admitted prior art ("AAPA"). This rejection is respectfully traversed.

The claimed invention relates to a method of providing a customer-oriented integrated product and service package for a surgical procedure. As such, amended independent claim 1 recites a method of "providing a customer-oriented integrated product and service package for a surgical procedure" by *inter alia* "providing predetermined specifications and conditions of a patient from a medical provider to a service provider" and "subsequently customizing, at a tissue bank, an allograft to be used in a predetermined surgical procedure, the allograft being customized to the predetermined specifications and conditions of the patient and of the predetermined surgical procedure to be performed on the patient." Amended independent claim 1 also recites "coordinating, by the service provider, delivery of the customized allograft from the tissue bank to the medical provider, and loaning, by the service provider, graft specific surgical instrumentation to match specifications of the allograft and the procedure."

Filho relates to a "tooth implant which is obtained from a donor's jawbone." (Abstract). According to Filho, "[T]he tooth implant includes the root of the donor's tooth with the crown detached therefrom and a portion of the donor's jawbone which surrounds the root and is attached thereto." (Abstract). Filho teaches that "[T]he

implant is obtained by carefully harvesting the root with the attached portion of jawbone surrounding the root as a single unit from a donor individual.” (Abstract).

The subject matter of claims 1-4 would not have been obvious over Filho and AAPA, whether considered alone or in combination. Neither Filho nor AAPA discloses, teaches or suggests all limitations of amended independent claim 1. Filho is silent about “providing predetermined specifications and conditions of a patient from a medical provider to a service provider” or about “subsequently customizing, at a tissue bank, an allograft to be used in a predetermined surgical procedure, the allograft being customized to the predetermined specifications and conditions of the patient and of the predetermined surgical procedure to be performed on the patient,” as claim 1 recites. Filho teaches removal of a tooth portion (the root circumscribed with attached bone from the donor’s jaw) which can be “stored in a tooth bank for later implantation in a recipient when the demand arises” (col. 3, ll. 51-53), and not the steps of “providing predetermined specifications and conditions of a patient from a medical provider to a service provider,” much less “subsequently customizing, at a tissue bank, an allograft to be used in a predetermined surgical procedure, the allograft being customized to the predetermined specifications and conditions of the patient and of the predetermined surgical procedure to be performed on the patient,” as in the claimed invention.

Filho also fails to disclose the specific step of “coordinating, by the service provider, delivery of the customized allograft from the tissue bank to the medical provider, and loaning, by the service provider, graft specific surgical instrumentation to match specifications of the allograft and the procedure,” as claim 1 additionally recites.

AAPA does not rectify the deficiencies of Filho. AAPA does not disclose, teach or suggest “providing predetermined specifications and conditions of a patient from a medical provider to a service provider,” or “subsequently customizing, at a

tissue bank, an allograft . . . to the predetermined specifications and conditions of the patient,” or “coordinating, by the service provider, delivery of the customized allograft from the tissue bank to the medical provider, and loaning, by the service provider, graft specific surgical instrumentation to match specifications of the allograft and the procedure,” as in the claimed invention.

AAPA teaches that delivery of the allograft is facilitated by a tissue bank and that, if necessary, instrumentation to be used to perform the procedure may be purchased, leased or borrowed from a provider or another medical facility. AAPA is silent, however, about providing information (specifications and conditions) about a patient, coordinating delivery of a customized allograft from a tissue bank to a medical provider, and loaning graft specific instrumentation, all provided by the same entity (i.e., the service provider), as in the claimed invention. In fact, AAPA teaches against the step of “coordinating, by the service provider, delivery of the customized allograft from the tissue bank to the medical provider, and loaning, by the service provider, graft specific surgical instrumentation to match specifications of the allograft and the procedure,” as AAPA specifically emphasizes that “[I]f the surgeon or medical facility does not already own the necessary instrumentation to be used to perform the procedure, then separate arrangements must also be made to purchase, lease or borrow the appropriate instruments through a provider or another medical facility.” (¶[0005]; emph. addded).

For at least these reasons, the Office Action fails to set forth a *prima facie* case of obviousness, and withdrawal of the rejection of claims 1-4 is respectfully requested.

Claims 5, 6, 14, 15 and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Filho in view of AAPA and further in view of Ramshaw et al. (U.S. Patent No. 5,791,907) (“Ramshaw”). This rejection is respectfully traversed.

Amended independent claim 14 recites a “method of providing a customer-oriented integrated product and service package for a surgical procedure” by “providing predetermined specifications and conditions of a patient from a medical provider to a service provider,” “customizing and sizing, by a tissue bank, an allograft according to the specifications and conditions of the patient and of a predetermined surgical procedure” and “arranging, by the service provider, for delivery of the customized allograft for the predetermined surgical procedure from the tissue bank to a medical facility at which the predetermined surgical procedure is to be performed.” Amended independent claim 14 also recites “providing, by the service provider, technical support and/or customer support to operating personnel before and/or during performance of the predetermined surgical procedure at the medical facility” and “providing training to operating personnel in the use of the instruments and skills to perform the surgical procedure.”

Ramshaw relates to an “interactive medical training device” that includes “a computer system having a display, wherein the computer system is programmed to provide education and training in medical procedures, including laparoscopic surgical procedures.” (Abstract). According to Ramshaw, “[T]his aspect is achieved by configuring the system to display, on a portion of the display, a video window” so that the video window “displays a prerecorded video segment illustrating a portion of a laparoscopic surgical procedure.” (Abstract).

The subject matter of claims 5, 6, 14, 15 and 17 would not have been obvious over Filho, AAPA and Ramshaw, whether considered alone or in combination. As noted above, Filho and AAPA do not disclose, teach or suggest all limitations of amended independent claim 1. Ramshaw fails to address the deficiencies of Filho and AAPA. Ramshaw teaches an interactive medical system for educating and training personnel in various medical procedures, and not providing predetermined

specifications and conditions of a patient from a medical provider (of a medical facility) to a service provider, or customizing allografts, or loaning graft instrumentation to match the specifications of the allograft, as in the claimed invention.

The cited references, considered alone or in combination, also fail to disclose, teach or suggest "providing predetermined specifications and conditions of a patient from a medical provider to a service provider," "customizing and sizing, by a tissue bank, an allograft according to the specifications and conditions of the patient and of a predetermined surgical procedure," "arranging, by the service provider, for delivery of the customized allograft for the predetermined surgical procedure from the tissue bank to a medical facility," "providing, by the service provider, technical support and/or customer support to operating personnel before and/or during performance of the predetermined surgical procedure at the medical facility" and "providing training to operating personnel in the use of the instruments and skills to perform the surgical procedure," as claim 14 recites. For at least these reasons, the Office Action fails to set forth a *prima facie* case of obviousness, and withdrawal of the rejection of claims 5, 6, 14, 15 and 17 is respectfully requested.

Claim 7 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Filho in view of AAPA and further in view of AORN Journal, *Association of Operating Room Nurses*, May 2000, Vol. 71, No. 5; Research Library ("AORN"). This rejection is respectfully traversed.

AORN relates to "flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning." (p. 1061). Specifically, AORN addresses questions and answers from nurses in operating rooms regarding sterilization of instruments or problems "the FDA has become aware . . . with cleaning, disinfecting, or sterilizing items leased by facilities." (p. 1062).

The subject matter of claim 7 would not have been obvious over Filho, AAPA and AORN, considered alone or in combination. As noted above, Filho and AAPA do not disclose all limitations of amended independent claim 1. AORN does not rectify the deficiencies of Filho and AAPA. AORN fails to disclose any of the limitations of claims 1 and 7. AORN does not disclose or suggest “customizing, at a tissue bank, an allograft to be used in a predetermined surgical procedure,” much less “customizing, at a tissue bank, an allograft to be used in a predetermined surgical procedure, the allograft being customized to predetermined specifications and conditions of a patient and of the predetermined surgical procedure to be performed on the patient” and “coordinating, by the service provider, delivery of the customized allograft from the tissue bank to the medical provider, and loaning, by the service provider, graft specific surgical instrumentation to match specifications of the allograft and the procedure,” as in the claimed invention.

AORN relates to various issues raised by nurses in operating rooms regarding sterilization, cleaning, or disinfecting of instruments, and not to methods of providing a customer-oriented integrated product and service package for a surgical procedure, much less to a method of providing a customer-oriented integrated product and service package for a surgical procedure by the specific steps of claim 1. For at least these reasons, the Office Action fails to set forth a *prima facie* case of obviousness, and withdrawal of the rejection of claim 7 is respectfully requested.

Claims 8-10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Filho in view of AAPA and further in view of Hamada (U.S. Patent No. 6,425,920) (“Hamada”). This rejection is respectfully traversed.

Amended independent claim 8 recites a “method of providing a customer-oriented integrated product and service package for a surgical procedure” by

"providing predetermined specifications and conditions of a patient from a medical provider to a service provider," "arranging, by the service provider, for delivery of a customized allograft for a predetermined surgical procedure, the customized allograft being sized, by a tissue bank, according to the specifications and conditions of the patient and of the predetermined surgical procedure" and "customizing, by the service provider, a surgical instrumentation kit specifically designed for use with the customized allograft and for performing the predetermined surgical procedure."

Amended independent claim 8 also recites "loaning, by the service provider, the customized surgical instrumentation kit to the customer for the performance of the surgical procedure."

Hamada relates to a spinal fusion implant. Hamada teaches "surgical instrumentation, implants, bone graft material, and measurement equipment to enable a spine fusion procedure to proceed more accurately, efficiently and safely by allowing precision measurement of the characteristics of the intervertebral space, selection of and provision of new implants, placement of an intervertebral implant." (Abstract).

The subject matter of claims 8-10 would not have been obvious over Filho in view of AAPA and Hamada, considered alone or in combination. Filho, AAPA and Hamada, alone or in combination, do not disclose or suggest all limitations of amended independent claim 8. None of the cited references discloses, teaches or suggests "providing predetermined specifications and conditions of a patient from a medical provider to a service provider," "arranging, by the service provider, for delivery of a customized allograft for a predetermined surgical procedure, the customized allograft being sized, by a tissue bank, according to the specifications and conditions of the patient and of the predetermined surgical procedure," "customizing, by the service provider, a surgical instrumentation kit specifically designed for use with the customized allograft and for performing the predetermined surgical procedure," and

"loaning, by the service provider, the customized surgical instrumentation kit to the customer for the performance of the surgical procedure," as claim 8 recites.

Filho teaches removal of a tooth portion (the root circumscribed with attached bone from the donor's jaw) which can be "stored in a tooth bank for later implantation in a recipient when the demand arises" (Col. 3, ll. 51-53), and not the specific steps recited in claim 8. AAPA and Hamada do not rectify the deficiencies of Filho.

AAPA does not disclose or suggest "providing predetermined specifications and conditions of a patient from a medical provider to a service provider," "arranging, by the service provider, for delivery of a customized allograft for a predetermined surgical procedure, the customized allograft being sized, by a tissue bank, according to the specifications and conditions of the patient and of the predetermined surgical procedure," "customizing, by the service provider, a surgical instrumentation kit specifically designed for use with the customized allograft and for performing the predetermined surgical procedure," and "loaning, by the service provider, the customized surgical instrumentation kit to the customer for the performance of the surgical procedure," as in the claimed invention.

AAPA teaches that delivery of the allograft is facilitated by a tissue bank and that, if necessary, instrumentation to be used to perform the procedure may be purchased, leased or borrowed from a provider or another medical facility. Thus, AAPA teaches against the steps of customizing a surgical instrumentation kit specifically designed for use with a customized allograft and loaning the customized surgical instrumentation kit to a customer, by the same entity (i.e., by the same service provider), as in the claimed invention.

Hamada relates to systems and methods for spinal fusion surgery, and not to customizing surgical instrumentation kits specifically designed for use with the customized allografts that are loaned to a medical provider for surgical procedures, as in the claimed invention. For at least these reasons, the Office Action fails to set forth a *prima facie* case of obviousness, and withdrawal of the rejection of claims 8-10 is respectfully requested.

Claims 11 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Filho in view of AAPA, Hamada and further in view of Ramshaw. Claim 13 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Filho in view of AAPA, Hamada and further in view of AORN. These rejections are respectfully traversed.

The subject matter of claims 11-13 would not have been obvious over the cited prior art references, whether considered alone or in combination. As noted above, Filho, AAPA, Hamada and Ramshaw, alone or in combination, do not disclose, teach or suggest all limitations of amended independent claim 8. For at least this reason, the Office Action fails to set forth a *prima facie* case of obviousness, and withdrawal of the rejection of claims 11-13 is also respectfully requested.

Allowance of the application is solicited.

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